

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY)
AVERAGE WHOLESAL PRICE LITIGATION)

MDL No. 1456

THIS DOCUMENT RELATES TO)
01-CV-12257-PBS AND 01-CV-339)

Civil Action No. 01-CV-12257 PBS

Judge Patti B. Saris

Chief Magistrate Judge Marianne B. Bowler

**MOTION OF DEFENDANTS BRISTOL-MYERS SQUIBB COMPANY, ONCOLOGY
THERAPEUTICS NETWORK CORP. AND APOTHECON, INC. TO COMPEL THE
PRODUCTION OF DOCUMENTS BY PLAINTIFFS AND MOTION FOR A
PROTECTIVE ORDER AGAINST A DEPOSITION NOTICE**

Defendants Bristol-Meyers Squibb Company, Oncology Therapeutics Network Corp. and Apothecon, Inc. (collectively, "BMS") submit this memorandum, together with the Declaration of Lyndon M. Tretter, Esq. ("Tretter Declaration"), in support of their motion (A) to compel the production of documents from two plaintiffs (1) New York Statewide Senior Action Council, Inc. ("Statewide") and (2) United Food and Commercial Unions and Employers Midwest Health Benefits Fund ("UFCW") and (B) for a protective order against a retaliatory deposition notice served against BMS.

Summary of Argument

The facts concerning this discovery dispute are set forth in the Tretter Declaration. Briefly, Statewide has failed to respond to BMS' discovery requests made at the deposition of its Executive Director five months ago (which requests, at the insistence of Statewide's counsel, were confirmed in a separate writing). BMS has telephoned, written and e-mailed Statewide's counsel to obtain compliance with its discovery demands – all to no avail. Statewide should be compelled to produce the requested documents.

UFCW has similarly failed to provide documents that it had agreed to produce, including e-mails and other documents stored electronically and unredacted versions of minutes of

its Board of Trustees meetings. It is fundamentally unfair for plaintiffs to demand that defendants perform extensive searches of their electronic files and produce full documents when they themselves will not do so. UFCW should be ordered to produce this material.

Moreover, UFCW has objected to one category of discovery primarily on relevance grounds: data relating to money it has allegedly paid on behalf of its members for physician services incidental to administering injectable or infusible drugs, such as chemotherapy agents.¹ UFCW is willing to produce only its payments for the drugs themselves, but not for the related physicians' services of administering the drugs or the charge by the physicians for the office visit. As BMS has argued to plaintiffs and will demonstrate to this Court, there is a large body of evidence that most payers -- whether the federal government under Medicare or private insurers like Blue Cross/Blue Shield entities (one of whom UFCW uses) -- view reimbursement for physician-administered drugs and the administrative services the physician provides as intertwined. (The doctor can make a profit off the drug, the service of infusing the patient with the drug, or both). Accordingly, it is not possible to evaluate UFCW's allegation that it overpaid for physician-administered drugs without knowing how much it was charged for the services component of the office visit.

Not only is the data BMS seeks highly relevant, but its production will not be burdensome to UFCW. If anything, UFCW has had to take extra steps to excise from the data relating to its members' entire medical claims all information except that relating to the drug

¹ Physician-administered drugs are to be distinguished from pharmacy-dispensed drugs. The former are primarily injectables that are administered by a medical professional to a patient in a doctor's office or medical facility. The latter are more likely to be pills or liquids that can be self-administered by the patient at home after picking them up from the pharmacy. UFCW and the other plaintiffs in this case purport to sue on behalf of payers for both categories of drugs.

reimbursement itself. The Court should order UFCW to produce the entire data set for all claims in which UFCW is seeking damages for payments for physician-administered drugs.²

Finally, plaintiffs have sought to punish BMS for seeking the full claims data by propounding a retaliatory Fed. R. Civ. P. 30(b)(6) notice. They seek a BMS witness with knowledge of (a) Medicare's and insurance companies' strategies for reimbursing physician-administered drugs together with related services and (b) the actions BMS takes, in pricing its drugs, in response to these strategies. This is silly. BMS witnesses do not have personal knowledge of the strategies of these payers; rather, these strategies are matters that counsel have discovered in defending this case. Moreover, at least in the private sphere, each negotiation between a physician and a payer is different on the issue of the physician's compensation for the drug and/or for the service of administering the drug. BMS does not and cannot change its pricing practices in light of thousands of negotiations of which it is unaware. Accordingly, the Court should issue a protective order against this Rule 30(b)(6) notice directed to BMS.

Background

Most of the discovery disputes involved in this motion, such as the failure to provide documents requested after a deposition or to search thoroughly for electronically-stored documents do not need a great deal of background explanation beyond that in the Tretter Declaration and, therefore, BMS will defer further discussion of those matters to the Argument section below. However, to appreciate truly the lack of merit in UFCW's objection to producing its full claims data relating to physician-administered drugs, it is useful to review the evidence of

² UFCW objects to producing another category of documents primarily on burden grounds: those documents that reflect subrogation or reimbursement it received from third-parties (such as workers' compensation insurers) for prescription drug expenditures it initially made on behalf of its members. Because UFCW cannot properly sue defendants for expenditures for which it has been reimbursed, BMS believes that UFCW should be compelled to identify those expenditures.

the link made by payers between the amount the physician will be reimbursed for a drug and the amount he or she will be reimbursed for the associated service of administering the drug.

Until very recently, drugs covered under Medicare, the federal government health program for seniors, have been limited mostly to physician-administered drugs. Since 1992, Medicare has paid for these drugs based on a measure called Average Wholesale Price ("AWP"), which appears in various trade publications. Since that time, the services for administering the drugs have been based on certain procedure codes and physician office overhead and practice payment components that are set out in minute detail in federal regulations.

Medicare has paid for the drugs based on AWP even though scores of studies have shown that physicians are able to obtain the drugs themselves at significant discounts to AWP and therefore are able to make profits when they are reimbursed by the program based on 100% or 95% of AWP. These studies, as well as changes made to the reimbursement regime under the 2003 Medicare Modernization Act, establish conclusively that the federal government has chosen to use the profits doctors make on the drugs to "cross-subsidize" the inadequate payments they receive for the incidental services related to administering the drugs and for the unaccounted-for costs to practitioners like oncologists who have very high overhead.

As former Senator (now Attorney General) Ashcroft stated in the Congressional Record:

While there are indications that drug reimbursements [under Medicare] have often exceeded doctors' and hospitals' costs, these margins have been used to help cover costs for professional services, which are inadequately reimbursed according to the cancer community, the General Accounting Office and HFCA itself.

146 CONG. REC. S8019-05, S8022 (Sept. 5, 2000) (emphasis added) (annexed hereto as Ex. A).

Effective 2004, the Medicare Modernization Act lowered the payment for physician-administered drugs to 85% of AWP but simultaneously provided that reimbursement for physicians' services would be increased to make up for the shortfall doctors would experience because of lower drug reimbursement. Medicare Modernization Act of 2003, H.R. 1, 108th Cong. §§303(b)(2) and 303(f) (2003). Beginning in 2005, reimbursement for drugs will no longer be based on AWP at all and, as recent newspaper articles have noted, many physicians are concerned that that they will not make enough on the services component of Medicare to continue to treat patients. See, e.g., Fears Voice on Bush Medicare Plan, BOSTON GLOBE, July 28, 2004, at E2 (annexed hereto as Ex. B); Sarah Lueck, *Cancer-Drug Reimbursement Cuts*, WALL ST. J., July 27, 2004, at D4 (annexed hereto as Ex. C).

Obviously, there is an interplay or trade-off between Medicare's reimbursement of physician-administered drugs and physicians' related services. Although defendants do not rely on its conclusions or methodologies, a recent study of Blue Cross/Blue Shield entities (often cited by plaintiffs) states that this same effect exists in the sphere of private reimbursement for physician-administered drugs and services. The authors wrote:

Approximately one-third of the health plans [surveyed] indicated that they are either planning or are seriously considering moving to a more aggressive pricing approach for [reimbursing] physician-administered drugs in 2003. A number of these health plans recognize that the fees for the drug administration procedure codes may be too low and [these administration] fees may be increased if drug prices are lowered.

Z. Dykman & P. Hess, *Survey of Health Plans Concerning Physician Fees and Payment Methodology*, at 17 (June 2003) (unpublished survey prepared for The Medicare Payment Advisory Commission) (emphasis added) (annexed hereto as Ex. D).

Given the overwhelming evidence that public and private payors view the reimbursement rates for physician-administered drugs and related services to be inextricably intertwined, UFCW's position that information about the amounts it paid for physicians' services related to drug administration is not "relevant" for discovery purposes is totally without merit.³

Argument

POINT I

STATEWIDE SHOULD BE COMPELLED TO PRODUCE

Plaintiff Statewide's dereliction of its discovery obligations is manifest. As the Tretter Declaration states, at the deposition of Statewide's Executive Director it became clear that certain documents that were the subject of outstanding demands had not been provided. BMS' counsel also requested that Statewide produce certain documents referred to by its Executive Director during the course of the deposition. At the insistence of Statewide's counsel, BMS confirmed all of these requests in writing. That was four months ago. Statewide and its counsel have ignored that letter as well as numerous follow-up letters, voice-mails and e-mails. An oral request at deposition followed-up in writing does not differ from a formal document request pursuant to Federal Rule 34. Statewide has an obligation to respond to BMS' document requests and at this point, Statewide should be compelled by a Court order to produce the requested documents within five (5) days of its Order. Carroll v. Acme-Cleveland Corp., 1989 WL 152561

³ It is also interesting to note that UFCW has been willing to provide data concerning the services portion of its payments for *pharmacy-dispensed* drugs, but not for the services components of its payments for *physician-administered* drugs. Pharmacy-dispensed drugs are often reimbursed by payers based on at least two factors – an "ingredient cost" for the drug itself and a "dispensing fee" to the pharmacist for the services of storing, compounding and dispensing the drug. Inexplicably, UFCW has provided defendants with the amounts it allegedly paid in both ingredient costs and dispensing fees for pharmacy-dispensed drugs, but only the ingredient costs for physician-administered drugs.

at *1 (N.D. Ill. Dec. 6, 1989) (finding that requests made at a deposition and subsequently followed-up by letter comply with Fed. R. Civ. P. 34).

POINT II

UFCW SHOULD BE COMPELLED TO PRODUCE

A. Electronic Documents, Unredacted Minutes & Subrogation Records

1. *Electronic Documents*

On June 23, 2004 UFCW agreed that it would produce all electronic documents by July 2, 2004. (See Tretter Declaration, Ex. 10). On August 20, 2004, UFCW produced a handful of e-mails and other electronic documents that date primarily from the period December 2003 to July 2004 and that appear to come from only two employees' very recent files. (See Tretter Declaration ¶ 18). This is not a good faith search. UFCW should be required to search the hard-drives of all employees likely to have responsive documents as well as any servers or other central storage areas. Also, UFCW commenced its first suit on AWP-related matters in November 2001.⁴ Unless UFCW failed to preserve electronic documents, it should have materials going back to at least that time. UFCW should be required to conduct a complete search and produce responsive materials within five (5) days of the Court's Order.⁵

2. *Unredacted Meeting Minutes*

Among the documents requested from UFCW were the minutes of any trustee meetings. (See Tretter Declaration, Ex. 5, at document request # 25). UFCW did produce a number of meeting minutes, however, many of these produced documents contained large portions

⁴ The first suit UFCW filed against any pharmaceutical company was on November 15, 2001 in the Northern District of Illinois against Baxter International, Inc.

⁵ On the other hand, if UFCW really has destroyed responsive documents dated after it brought suit, other discovery sanctions may be in order.

that were redacted, purportedly based upon attorney-client privilege. (See Tretter Declaration, Ex. 6).

BMS objected to the production of redacted minutes because it was clear from the portions of the minutes that were produced that third-parties had been present at the meetings and that, therefore, no privilege attached. (See Tretter Declaration ¶ 15 & 16).⁶ UFCW's counsel replied that UFCW wanted to "investigate" whether the third-parties were excused during the relevant portions of the meetings. (Tretter Declaration ¶ 16). However, UFCW never came forward with any evidence to support their assertion of privilege. Indeed, it never responded at all.

UFCW has the burden of establishing the basis for its assertion of privilege. Digital Equipment Corp. v. Currie Enterprises, et al., 142 F.R.D. 8, 15 (D. Mass. 1991) (the burden of establishing the existence of the attorney-client privilege . . . rests with the party resisting discovery). UFCW has failed to provide any information from which one could reasonably conclude that the redacted portions of the minutes are privileged documents. Id. (citing the four factors a party must show to sufficiently allege an assertion of attorney-client privilege); see also FTC v. Shaffner, 626 F.2d 32, 37 (7th Cir. 1980) (The burden is on the party claiming the privilege to present the underlying facts demonstrating the existence of the privilege). Indeed, UFCW has not produced any information beyond the mere assertion that an attorney was present or spoke at these meetings. The Court should compel it to produce the unredacted minutes within five (5) days of its Order.

⁶ Attorney-client privilege applies only to communications between the attorney and the client. U.S. v. Cavallaro, 284 F.3d 236, 246-247 (1st Cir. 2002) (*citing* U.S. v. Ackert, 169 F.3d 136, 139 (2d Cir. 1999)). The presence of a third-party undermines any assertion of attorney-client privilege unless the third-party's presence is, like a translator, integral to the communication of the advice or necessary for the effective consultation between the attorney and the client. Id. The third parties present during the UFCW trustee meetings were benefit consultants. They were not retained by UFCW's counsel, nor did their presence relate to the allegedly privileged communications. (See Ex. 6).

3. *Documents Concerning Third-Party Reimbursements*

At his deposition, the Administrator for UFCW testified that UFCW is sometimes reimbursed by third-parties, such as workers' compensation insurers or insurers for plan participants' spouses, for prescription drug expenditures UFCW has made on participants' behalf. By letter dated May 13, 2004, BMS requested that UFCW identify those instances in which this happened so that UFCW would not be permitted to sue defendants for expenditures as to which it had recovered from another source. (See Tretter Declaration, Ex. 7). UFCW's counsel responded that it was too difficult for UFCW to produce such information. BMS maintains that either UFCW must produce this information so as to avoid double recoveries or must stipulate that it is unable to do so and suffer the consequences of not being able to prove damages.

B. Full Claims Data Relating To Physician-Administered Drugs

Defendants' submitted the following two discovery requests, among others, to all Plaintiffs in October 2003 (See Tretter Declaration, Ex. 5):

Document Request No. 15:

"All communications between you and Participants or Beneficiaries relating or referring to Subject Drugs, including, without limitation, invoices from Providers, payments to Providers, claims materials, marketing materials, coverage materials, benefit evaluations, benefit decisions, reimbursements, discounts or medigap coverage."

Document Request No. 16:

"All Documents relating or referring to any Participant or Beneficiary that bought Subject Drugs, including, without limitation, any co-payments made by any Participant or Beneficiary, and any damages arising from such purchases."

In addition, as set forth in the Tretter Declaration, BMS has specifically requested full claims data relating to UFCW's allegations concerning physician-administered drugs,

including but not limited to data relating to physicians' services and office visits. For the reasons dismissed in the Background section, supra, such claims data are clearly relevant.

The Federal Rules of Civil Procedure permit broad discovery of information related to the matters involved in a litigation. Fed. R. Civ. P. 26(b)(1). Viola v. Bensalem Township, 1986 WL 10525 at *2 (E.D. Pa. Sept. 24, 1986) (*citing* Schlagenhauf v. Holder, 379 U.S. 104 (1964)); see also U.S. v. IBM Corp., 66 F.R.D. 215, 218 (S.D.N.Y. 1974). A discovery request is relevant if there is any possibility that the information sought might be relevant to subject matter of the action. See Viola, 1986 WL 10525 at *2; see also IBM, 66 F.R.D. at 218. Furthermore, discovery is permitted unless it is clear that the information sought has no bearing to the claims at issue or will not lead to any admissible evidence. Wallace v. Abramson, 1988 WL 63065 at *4 (D.D.C. June 7, 1988) (granting plaintiff's motion to compel financial records that could substantiate their allegations of fraud against the defendant); Viola, 1986 WL 10525 at *2 (relying on the liberal standards of discovery to deny defendant's objections to the production of documents). The information Defendants seek regarding charges related to the actual administration of physician-administered drugs is highly relevant to an accurate determination of UFCW's alleged damages. See Wallace, 1988 WL 63065 at *4.

POINT III

BMS IS ENTITLED TO A PROTECTIVE ORDER AGAINST THE DEPOSITION

On July 8, 2004, UFCW's counsel sent a letter to BMS' counsel objecting to the discovery that BMS was seeking concerning full claims data on physician-administered drugs and enclosed a deposition notice directed to BMS on the same subject. (See Tretter Declaration, Ex. 12). Clearly, this notice is nothing more than a punitive measure intended to thwart BMS' further discovery into physician-administered drugs and to harass BMS. (See Tretter Declaration ¶ 20 &

Ex. 12.) There is no person at BMS who is knowledgeable about the topics listed in their deposition notice.

A protective order may be granted to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense. Fed. R. Civ. P. 26(c). While the liberal standard of discovery must be respected, a district court should limit the process when the potential for abuse is high. Centeno-Bernuy v. Becker Farms, 219 F.R.D. 59, 61 (W.D.N.Y. 2003) (citing Topo v. Dhir, 210 F.R.D. 76, 78 (S.D.N.Y. 2002)). BMS respectfully requests that this Court issue a protective order against the July 8, 2004 Rule 30(b)(6) deposition notice directed to BMS.

Conclusion

For the reasons set forth above, Defendants respectfully request an order:

1. Compelling Statewide to produce the documents requested in the letter to Edward Notargiacomo from Lyndon Tretter, dated April 26, 2004 (Tretter Declaration, Ex. 2), within five (5) days of the Court's order;
2. Compelling UFCW to perform a full search for all documents maintained in electronic form that are responsive to defendants' discovery demands within five (5) days of the Court's order;
3. Compelling UFCW to produce unredacted versions of its trustees' meeting minutes within five (5) days of the Court's order;
4. Compelling UFCW to identify, on or before October 1, 2004, those prescription drug expenditures during the alleged class period for which it was reimbursed in whole or in part by third-parties.

5. Compelling UFCW to produce, within five (5) days of the Court's order, full data for all claims involving physician-administered drugs during the alleged class period.

6. Protecting BMS from having to produce a witness in response to the July 8, 2004 Deposition Notice.

Respectfully submitted,

*Bristol Meyers Squibb Co., Oncology Therapeutics
Network Corp. and Apothecon, Inc.*

By their Attorneys,

/s/ Joseph E. Haviland
Thomas E. Dwyer Jr. (BBO No. 139660)
Joseph E. Haviland (BBO No. 643814)
DWYER & COLLORA, LLP
600 Atlantic Avenue
Boston, MA 02210
(617) 371-1000

Steven M. Edwards (admitted *pro hac vice*)
Lyndon M. Tretter (admitted *pro hac vice*)
HOGAN & HARTSON
875 Third Avenue
New York, New York 10022
(212) 918-3000

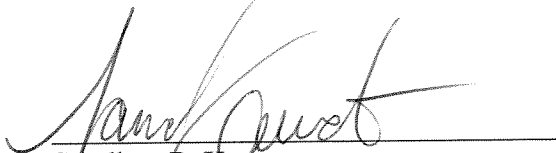
CERTIFICATE OF COMPLIANCE WITH LOCAL RULES 7.1 AND 37.1

Pursuant to Local Rules 7.1 (A)(2) and 37.1, and as demonstrated by the accompanying Tretter Declaration, counsel for Defendant BMS has conferred in good faith with opposing counsel and has attempted to resolve the issues addressed in this motion. Those efforts were unsuccessful.

/s/ Joseph E. Haviland
Joseph E. Haviland

CERTIFICATE OF SERVICE

I hereby certify that on August 27, 2004, I caused a true and correct copy of the foregoing Motion Of Defendants Bristol-Myers Squibb Company, Oncology Therapeutics Network Corp. And Apothecon, Inc. To Compel The Production Of Documents By Plaintiffs And Motion For A Protective Order Against A Deposition Notice and the Declaration Of Lyndon M. Tretter, Esq. In Support Of Defendant Bms' Motions (A) To Compel Certain Plaintiffs' Production Of Documents And (B) For A Protective Order Against A Deposition Notice, executed on August 27, 2004, to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456, by sending a copy to Verilaw Technologies for posting and notification.

A handwritten signature in black ink, appearing to read "Sandhya P. Kawatra", is written over a horizontal line.

Sandhya P. Kawatra
HOGAN & HARTSON
875 Third Avenue
New York, New York 10022